California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting
January 27, 2009

Sheraton Hotel - Mission Valley
1433 Camino Del Rio South
San Diego, CA, 92108
(619) 260-0111

1 – 5 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order **1 p.m.**

1. Welcoming Remarks
   Subcommittee Chair Ken Schell, PharmD
2. Review of Consumer Surveys Conducted by the Board of Pharmacy
3. Review of Survey Results from a Joint Survey Developed by the Pharmacy Foundation of California and the Board of Pharmacy
4. Review of California's Requirements for Prescription Container Labels (California Business and Professions Code Section 4076)
5. Timelines for Project Deliverables
6. Public Comment
7. Future Meeting Dates

Adjournment **5 p.m.**

Agenda Item 2

Consumer Surveys Conducted by the Board

Also

Minutes of the Forum on Designing Patient-Centered Labels November 20, 2008

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **January 18, 2009**

To: **SB 472 Subcommittee**

Subject: **SB 472 Consumer Surveys**

In May 2008, board staff developed a prescription label survey for distribution at public outreach events. The survey is available in English and Spanish, and a copy is provided on the following pages.

Since late May, board staff have been using the survey to interview attendees at public events. Consumers have been invited to complete surveys on-site during the events, or mail them to the board using the self-addressed envelopes provided. This method of soliciting information has proved less intimidating to consumers than individually speaking at public hearings. Board staff attending the community events has also reported positive feedback when discussing this initiative with the public. In October 2008, pharmacist and pharmacy associations agreed to share the surveys with their members to aid the board in data collection.

The survey can be completed and submitted electronically on the board's Web site at https://app.dca.ca.gov/pharmacy/survey_sb472.asp. It is also available on the board's Web site in Spanish. In addition, AARP invited consumers to "Put in Your Two Cents on Prescription Labeling" in the AARP September 2008 newsletter.

The board has also provided consumers with one-page fact sheets entitled, "Do you understand the directions on your Rx medicine label?" The fact sheet provides background information related to SB 472, and printed samples of faux prescription labels as a visual aid.

A total of 606 consumers completed board surveys as of January 13, 2009. The survey results of the board's consumer surveys follows this page. Not every consumer provided an answer to each question, while others provided multiple answers to individual questions. Many consumers gave the same response (i.e., larger font) to more than one question.

Trends have been identified in the answers provided thus far. Many responses suggest that the purpose of the drug be printed on the prescription label, and that a larger or bolder type font be used.

When asked what would make prescription labels easier to read, the top two responses were:

- Larger or bolder print
  (306 of 510 responses = 60.0%)
- Highlighting directions for use and other information in colors other than black
  (58 of 510 responses = 11.4%)

When asked what to change on the prescription label, the top three responses were:

- Print should be larger or darker
  (168 of 558 responses = 30.1%)
- No changes should be made to the label -- references were made to Target, Raley's, CVS and Kaiser labels
  (137 of 558 responses = 24.6%)
- Include purpose of the drug – state what condition the medication is intended to treat
  (67 of 558 responses = 12.0%)

When asked what information on the label was most important, the top three responses were:

- Directions for use
  (216 of 1,171 responses = 18.6%)
- Name of drug; if generic, brand name and generic
  (212 of 1,171 responses = 18.1%)
- Dosage prescribed
  (209 of 1,171 responses = 17.8%)

When asked for other suggestions, the top two responses were:

- Easy-open lids should be used; no child-proof caps for seniors
  (20 of 132 responses = 15.1%)
- Include purpose of the drug – state what condition the medication is intended to treat
  (16 of 132 responses = 12.1%)

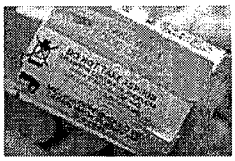
This year, the board is sponsoring legislation to add the purpose of the drug to the label if requested by the patient. Having the purpose of the drug listed on the label was stated as a response to the following three questions:

1. What information is most important to you: 81 of 1,171 responses = 6.9 percent
   or **81 of 606 individuals submitting surveys (13.4 percent)**
3. What would you change on the label: 67 of 558 responses = 12.0 percent
   or **67 of 606 individuals submitting surveys (11.1 percent)**
5. Other suggestions for improving the label: 16 of 132 responses = 12.1 percent
   or **16 of 606 individuals submitting surveys (2.6 percent)**

For information, following this page are the minutes of the November 20, 2009, Board of Pharmacy Meeting and Forum on Designing Patient-Centered Prescription Labels.

CONSUMERS – we want to hear from you!

Do you have suggestions to improve prescription container labels? The California State Board of Pharmacy welcomes your feedback to make labels more patient-friendly with directions that are easier to read and understand.



Examples of warning labels

Examples of different container shapes and sizes requiring different types of labels

What information on the label is most important to you?

_____

_____

Do you understand the directions?

_____

_____

What would you change on the label?

_____

_____

What would make the label easier to read?

_____

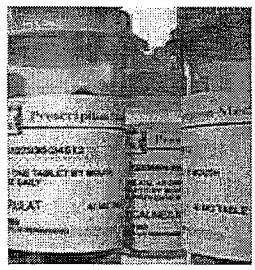
_____

Other suggestions:

_____

_____

City: _____ **Date:** _____



Printed information in different colors

Directions for use or how to take the drug

THANK YOU for your feedback.
Please return your completed form to:

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834

CONSUMIDORES – ¡Queremos oír de usted!

¿Tiene usted sugerencias para mejorar las etiquetas del envase de recetas? La Junta de Farmacia del Estado de California da la bienvenida a su reacción para hacer etiquetas más-paciente amistosas con las indicaciones que son más fáciles de leer y comprender. Gracias por su reacción.

¿Qué información en la etiqueta de la receta es más importante para usted?

¿Comprende usted las instrucciones en la etiqueta de la receta?

¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ **Fecha:** _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

CONSUMIDORES – ¡Queremos oír de usted!

¿Tiene usted sugerencias para mejorar las etiquetas del envase de recetas? La Junta de Farmacia del Estado de California da la bienvenida a su reacción para hacer etiquetas más-paciente amistosas con las indicaciones que son más fáciles de leer y comprender. Gracias por su reacción.

¿Qué información en la etiqueta de la receta es más importante para usted?

¿Comprende usted las instrucciones en la etiqueta de la receta?

¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ **Fecha:** _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

CALIFORNIA STATE
BOARD OF PHARMACY

Do you understand the directions on your Rx medicine label?

Approximately 46% of American adults do not.

A prescription label says to "Take two tablets by mouth twice daily." Sounds simple, doesn't it?

But patients have understood this to mean:

- Take it every 8 hours
- Take it every day
- Take one every 12 hours

Better directions might be "Take 2 tablets by mouth at 8 in the morning, and take 2 tablets at 9 at night."

FACT: Six out of 10 people have taken their medicines incorrectly, due to:

- confusing directions on the container label,
- poor health literacy (the ability to read, understand, and act on healthcare information), and
- inability to read and/or understand directions written in English of those whose first language is not English.

FACT: Medicine errors are among the most common medical errors, harming at least 1.5 million people every year. More than one third of these take place outside a hospital in a home setting, costing close to $1 billion annually.

FACT: Up to one-half of all medicines are taken incorrectly or mixed with other medicines that can cause dangerous reactions that can lead to injury and death.

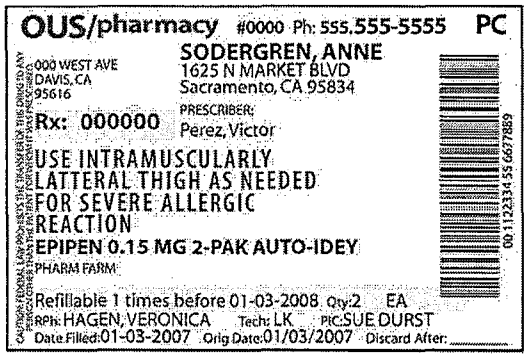
Medicine-related errors must be reduced. One way to begin is by providing patients with easy to read and understand prescription container labeling. This can be a giant step toward increasing consumer protection and improving the health, safety, and well-being of consumers.

California recognizes the importance of improving medicine container labels. In 2007, the Legislature and Governor Schwarzenegger enacted Senate Bill 472, mandating the Board of Pharmacy to develop requirements for standardized, patient-centered, prescription drug labels on all prescription medicine dispensed to patients in California.

In 2008, the Board will hold statewide public meetings to consult with patients and health providers to improve prescription container labels. The meetings will focus on improving directions for the drug's use, using better type fonts and sizes, and placement of information that is patient-centered. The needs of senior citizens and patients with limited English reading skills also will be identified.

(916) 574-7900
WWW.PHARMACY.CA.GOV
1625 N. MARKET BLVD
SUITE N-219
SACRAMENTO, CA 95834

sample prescription labels



OUS/pharmacy #0000 Ph: 555.555-5555 PC

000 WEST AVE
DAVIS, CA
95616

SODERGREN, ANNE
1625 N MARKET BLVD
Sacramento, CA 95834

Rx: 000000

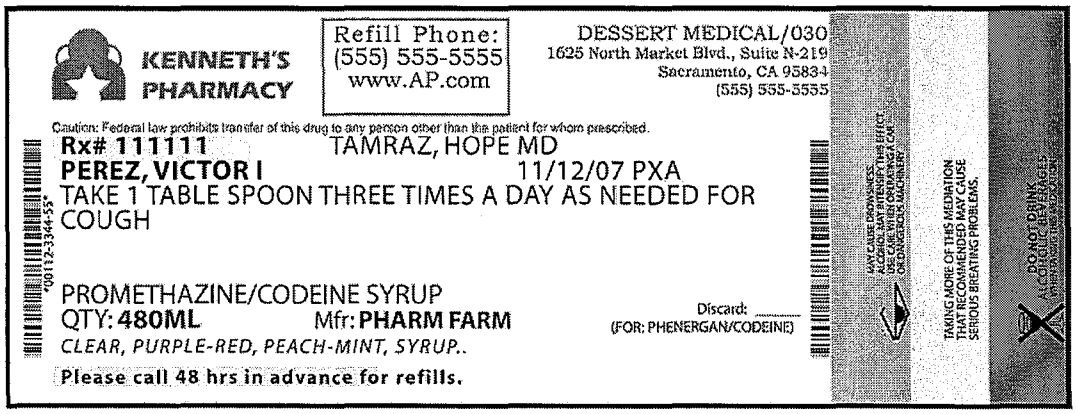
PRESCRIBER:
Perez, Victor

USE INTRAMUSCULARLY
LATTERAL THIGH AS NEEDED
FOR SEVERE ALLERGIC
REACTION
EPIPEN 0.15 MG 2-PAK AUTO-IDEY
PHARM FARM

Refillable 1 times before 01-03-2008 Qty:2 EA
RPh: HAGEN,VERONICA Tech: LK PIC:SUE DURST
Date Filled:01-03-2007 Orig Date:01/03/2007 Discard After: _____

00 1122334 55 6677889

CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.



KENNETH'S PHARMACY

Refill Phone:
(555) 555-5555
www.AP.com

DESSERT MEDICAL/030
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834
(555) 555-5555

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.

Rx# 111111 TAMRAZ, HOPE MD
PEREZ, VICTOR I 11/12/07 PXA
TAKE 1 TABLE SPOON THREE TIMES A DAY AS NEEDED FOR COUGH

PROMETHAZINE/CODEINE SYRUP
QTY: 480ML Mfr: PHARM FARM
CLEAR, PURPLE-RED, PEACH-MINT, SYRUP..

Please call 48 hrs in advance for refills.

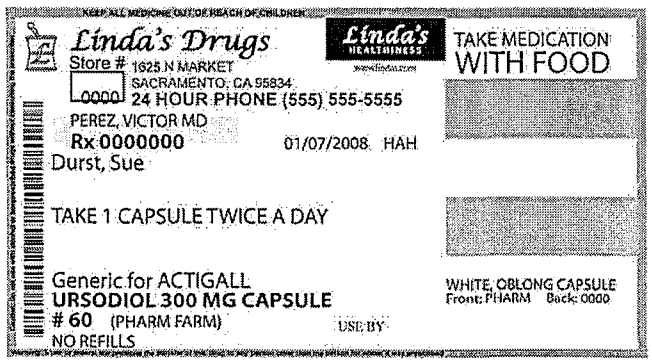
Discard: _____
(FOR: PHENERGAN/CODEINE)

00112-3344-55

AVOID DRIVING OR OPERATING HEAVY MACHINERY

TAKING MORE OF THIS MEDIATION THAT RECOMMENDED MAY CAUSE SERIOUS BREATHING PROBLEMS.

DO NOT DRINK ALCOHOLIC BEVERAGES



KEEP ALL MEDICINE OUT OF REACH OF CHILDREN

Linda's Drugs
Store # 0000
1625 N MARKET
SACRAMENTO, CA 95834
24 HOUR PHONE (555) 555-5555

Linda's HEALTHINESS

TAKE MEDICATION WITH FOOD

PEREZ, VICTOR MD
Rx 0000000 01/07/2008 HAH
Durst, Sue

TAKE 1 CAPSULE TWICE A DAY

Generic for ACTIGALL
URSODIOL 300 MG CAPSULE
60 (PHARM FARM)
NO REFILLS

USE BY

WHITE, OBLONG CAPSULE
Front: PHARM Back: 0000

California State Board of Pharmacy Prescription Label Survey

OBJECTIVE: To elicit feedback from consumers in California regarding development of patient-centered prescription drug labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007)

METHODOLOGY: A survey was developed by the California State Board of Pharmacy (Board) in May 2008. The questions were open-ended, allowing participants to provide as little or as much information as desired. Board staff used the survey to interview consumers at public outreach events including health/community fairs in Sacramento, Elk Grove, Los Angeles, Riverside, San Diego, Merced, and San Francisco. Printed surveys and self-addressed return envelopes were provided to attendees who chose to return responses by mail. The survey was provided in English and Spanish. The board also provided fact sheets entitled, "Do you understand the directions on your Rx medicine label?" and samples of faux prescription labels serving as visual aids. The survey was posted on the Board's public website and to interested parties and organizations including the Gray Panthers and the Latino Coalition for a Healthy California. Board members also interviewed consumers, and returned the responses by mail.

RESULTS: A total of 606 surveys were received as of January 13, 2009. The majority of respondents provided one or more answers to the first two questions, but did not always provide answers to subsequent questions. Respondents gave similar answers to multiple questions within a survey (i.e., request for large print). Attached graphs reflect detailed responses; most frequent responses summarized below.

When asked what information on the prescription label was most important, the top responses were:

Directions for use (218 of 1,171 responses = 18.6%)
Name of drug; if generic, state generic name AND brand name (212 of 1,171 responses = 18.1%)
Dosage prescribed (209 of 1,171 responses = 17.8%)
Side effects/warnings/interactions/contraindications (121 of 1,171 responses = 10.3%)
Purpose of drug – state what condition medication is prescribed to treat (81 of 1,171 responses = 6.9%)

When asked what to change on the prescription label, the top responses were:

Print should be larger or darker (168 of 558 responses = 30.1%)
Nothing needs to be changed on the label (137 of 558 responses = 24.6%)
Include purpose of drug – state what condition medication is intended to treat (67 of 558 responses = 12%)

When asked what would make prescription labels easier to read, the top response was:

Larger or bolder print (306 of 510 responses = 60%)

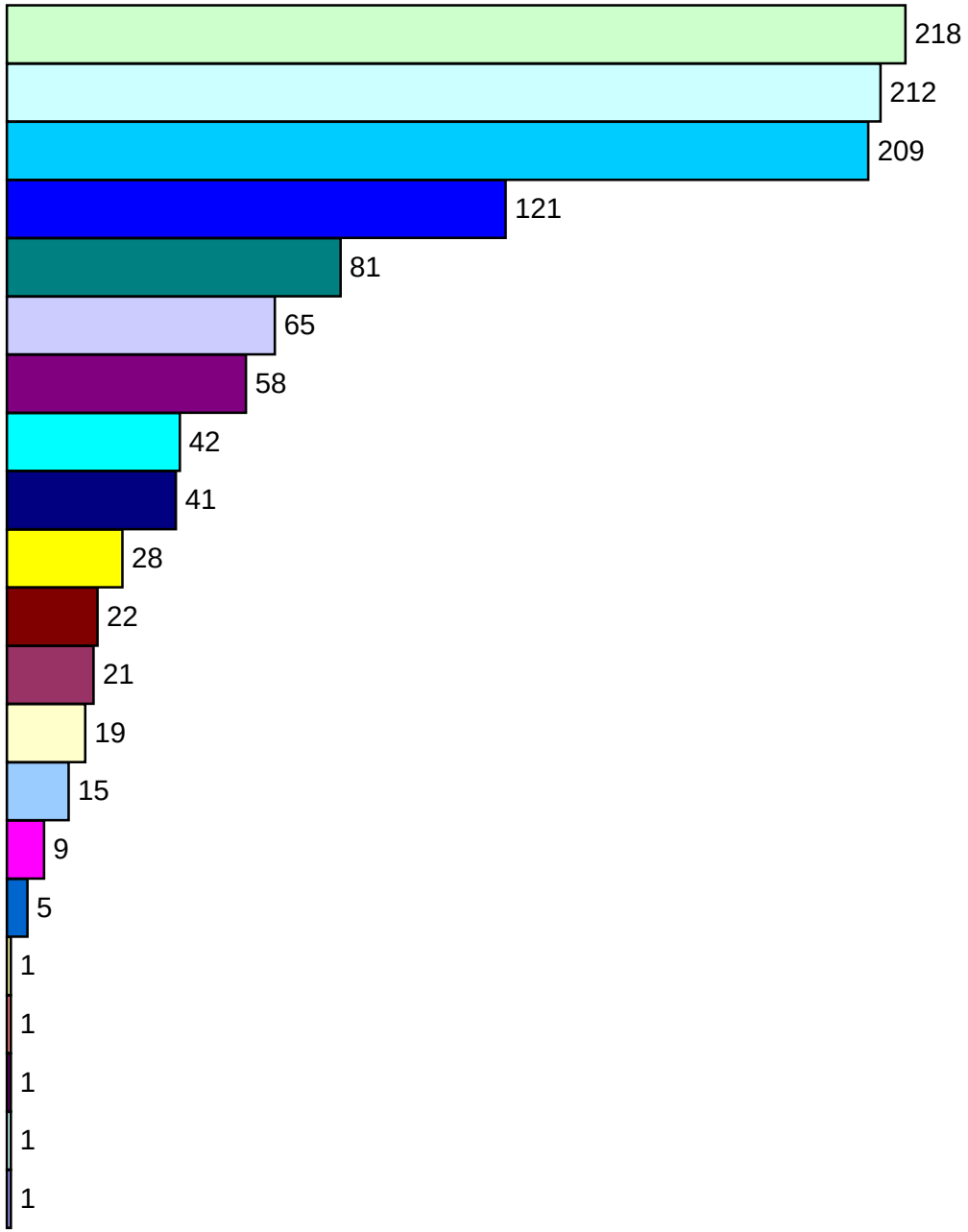
When asked for other suggestions, the top responses were:

Easy-open lids/packages should be used; no child-proof caps for seniors (20 of 132 responses = 15.1%)
Include purpose of drug - state what condition medication is intended to treat (16 of 132 responses = 12.1%)

CONCLUSIONS: Most consumers participating in this survey requested larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. They also noted that color printing and highlighting on labels brings attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

QUESTION #1: What information on the label is most important to you?

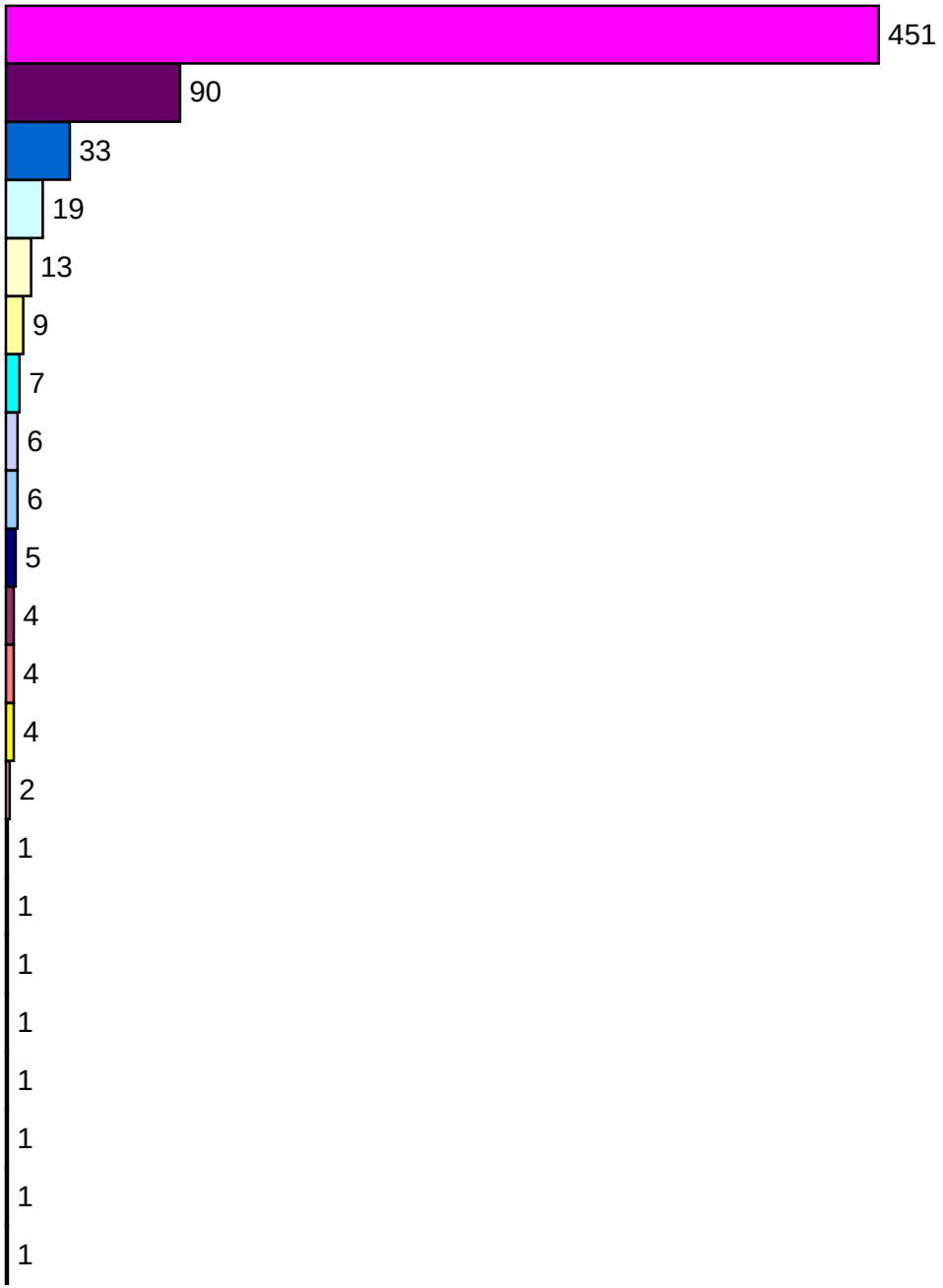
606 surveys returned (1,171 responses to Question #1) as of January 13, 2009



- Name of drug; if generic, state generic name AND brand name
- Dosage prescribed
- Side effects/warnings/interactions/contraindications
- Purpose of drug; what condition medicine is intended to treat
- Specific times during day to take medicine (and with, w/o food)
- Refill renewal/reorder information/expiration; date filled
- Patient name (some also suggested patient's date-of-birth)
- Expiration date of drug
- Large or bold print
- Phone numbers (NOT printed in close proxemity to each other)
- Prescribing doctor's name
- Description of pill (shape/color)
- Prescription number
- All information on label is important
- Name of drug store/pharmacy/pharmacist
- With a large family, keep all prescriptions in the same place
- Diabetes information
- Highlighting information including directions for use
- Basic measurements (e.g., teaspoons, not milligrams)
- Don't hide important information under another label

QUESTION #2: Do you understand the directions on the prescription label?

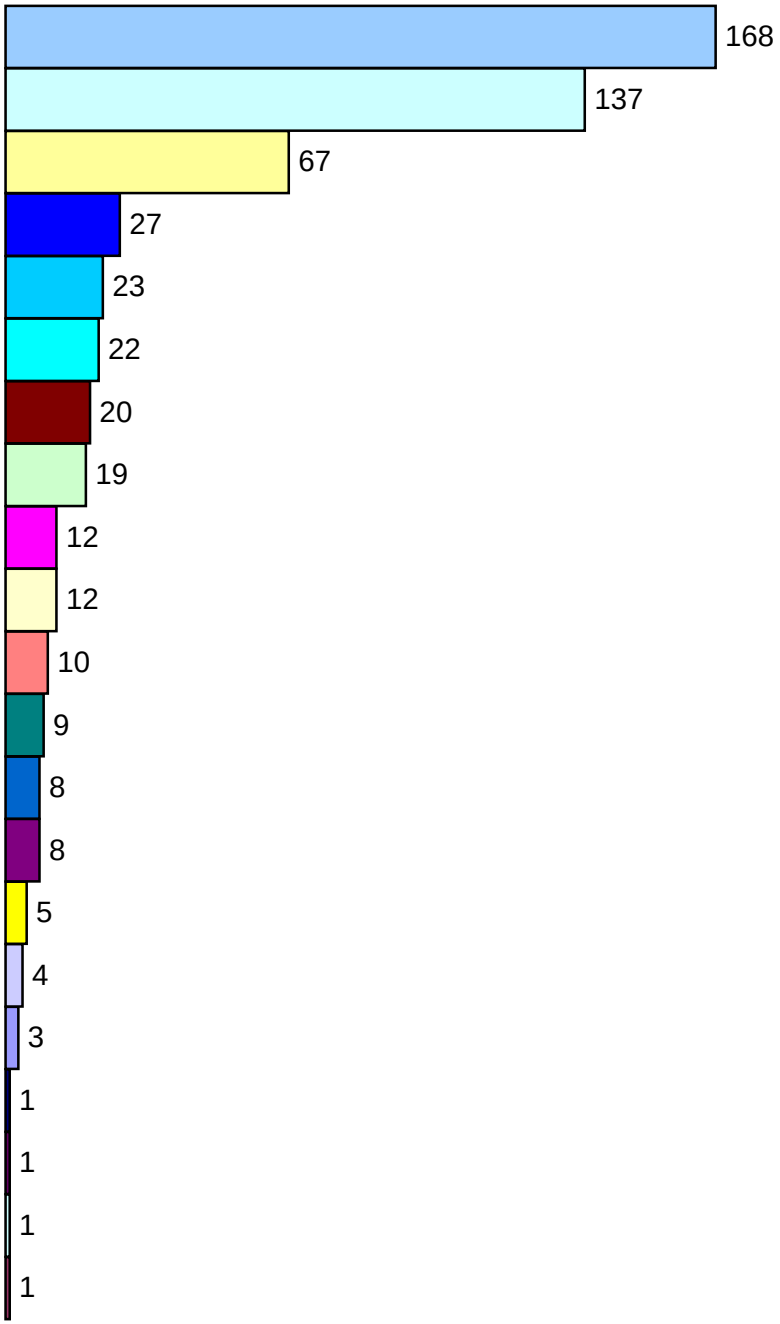
606 surveys returned (661 responses to Question #2) as of January 13, 2009



- Yes
- Usually (though print may be too small, directions/warnings unclear)
- Sometimes
- No (i.e., trouble understanding or not enough space for directions)
- Directions should state what time(s) to take medicine and how much
- Would be helpful to know whether to take with or without food
- I understand because I'm RN, Dr, health worker, have biology degree
- Not when there is a language barrier
- What does 2x (or 3x, or 4x) a day mean?
- Directions need clarity (2 pills = 1 pill twice/day or 2 pills twice/day?)
- Instructions should be in English and Spanish
- Instructions should be in English and Spanish
- Abbreviations should be eliminated
- I do not understand directions that only say "Take as directed"
- No long paragraphs on prescription label
- Label from Kaiser understandable, label from Rite Aid not as clear
- Bullets and spacing on label would be helpful
- Handout should be more readable
- Accompanying paper shouldn't be complicated - use bullets/spacing
- When I don't understand the directions, I ask the pharmacist
- Pharmacist's directions are vague during consultation
- The directions often conflict with the doctor's orders

QUESTION #3: What would you change on the prescription label?

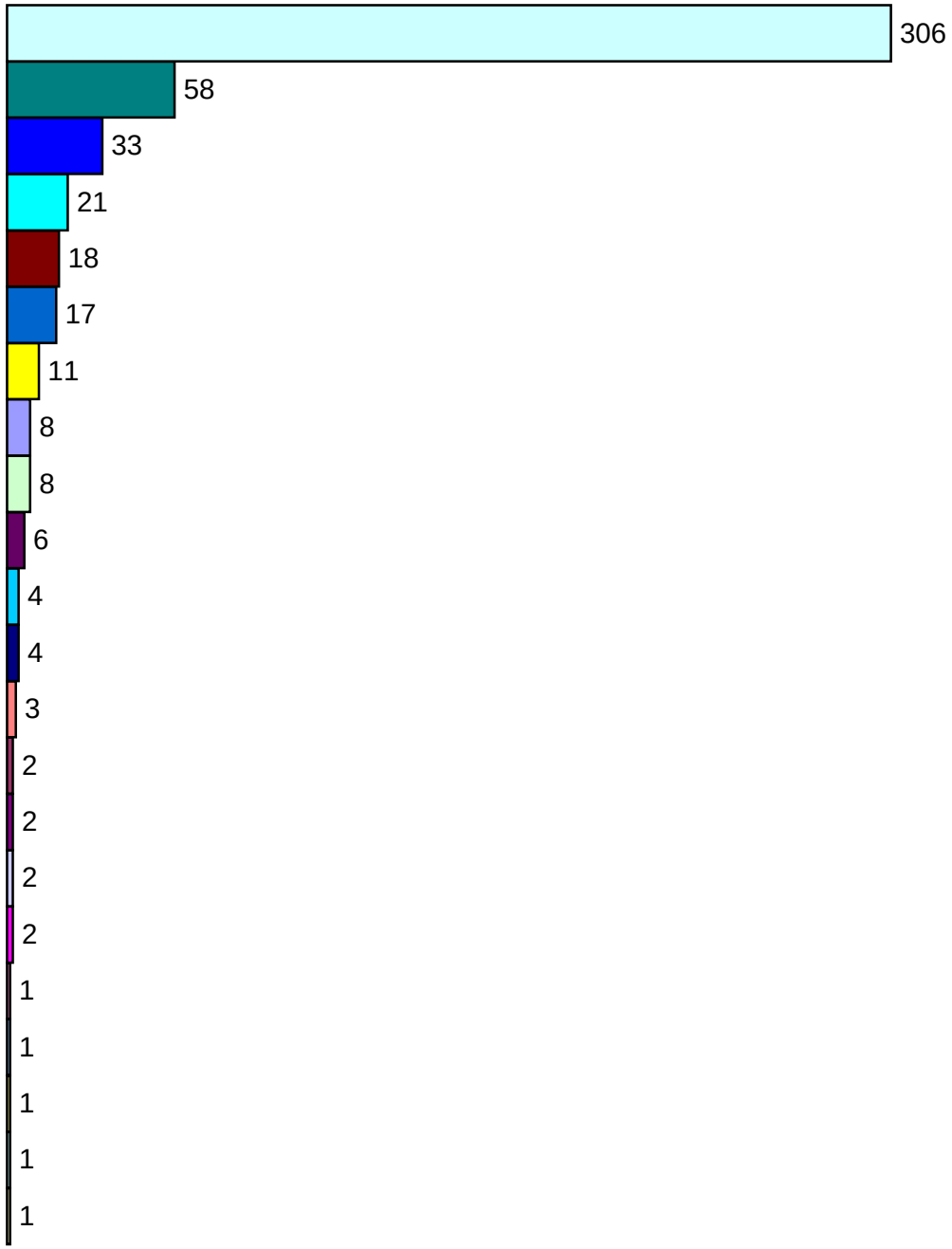
606 surveys returned (558 responses to Question #3) as of January 13, 2009



- Print should be larger or darker (legibility)
- Nothing needs to be changed (some referred to Kaiser, Target, Raley's, CVS)
- Include purpose of drug - state what condition medication is intended to treat
- Information printed should be understandable for all ages; layman's terms
- Use bold or highlighted print or capital letters; red/blue ink for warning labels
- Use different colors for different medicines, strengths/doses, family members
- Directions should include specific times (or morning/night) to take medicine
- Make warning labels easier to read or print directly on label instead of auxilliary
- Name of drug; if generic, state generic name AND brand name
- Refill info (i.e., date to reorder or if no refills remain, state "0 refills remain")
- Include direct phone numbers for easier communication with doctor/pharmacy
- Print in patient's primary language; bilingual wording
- Standardize location of info; uniform label; show information in same order
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Should be less advertising on label; remove unnecessary information
- Use ink that does not disappear, fade, rub off, or smudge
- Make "fold-out" label or "lift-open flap" stating side effects or purpose of drug
- If more than 1 label, show as "label #1" and "label #2"
- Use only one color on label
- More than one name for medicine is confusing at times
- Label should not refer patient to internet web site

QUESTION #4: What would make the prescription label easier to read?

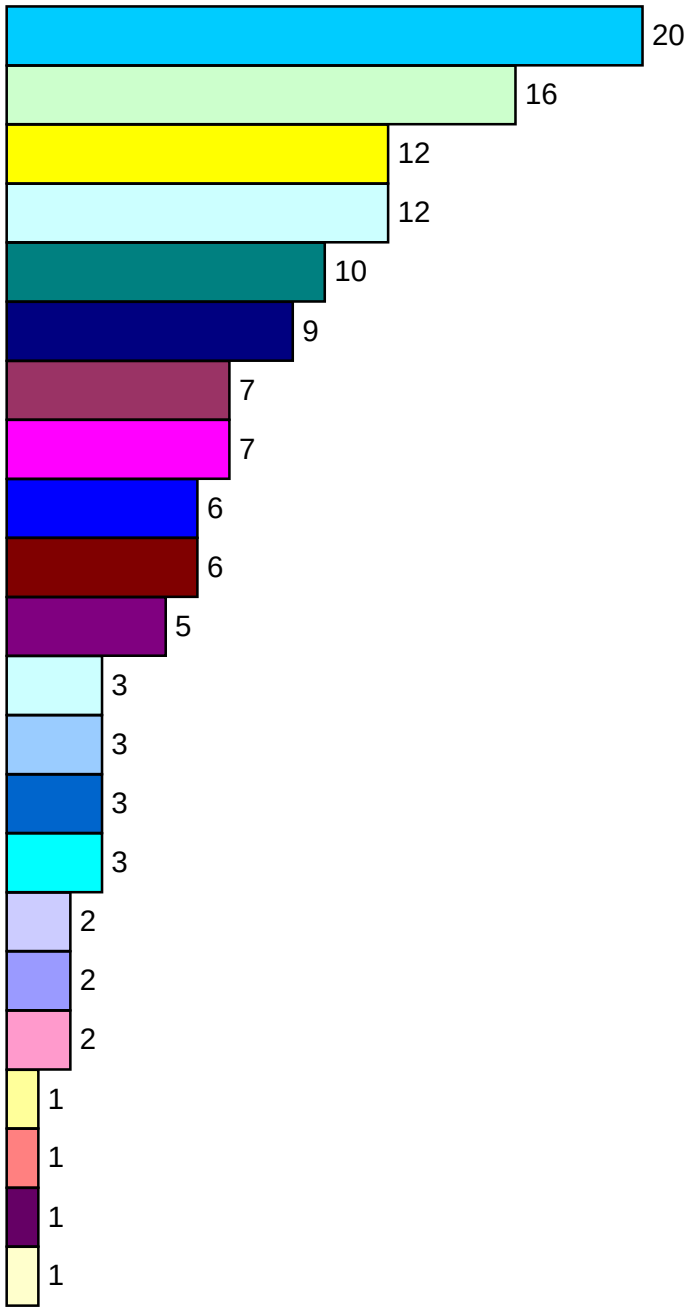
606 surveys returned (510 responses to Question #4) as of January 13, 2009



- Larger print (or bolder print)
- Highlighting directions & other info in colors (or color-coded label)
- Nothing
- Info should be in layman's terms; easy wording; don't abbreviate
- Bilingual wording
- Better description of directions (how/when to take; interactions)
- Refill renewal information including renewal expiration date
- Increase container size so large labels can have large print
- Eliminate clutter (i.e., multiple colors, icons, logos, name of PIC)
- Standard labeling for all pharmacies; standard placement of info
- Underline info or separate directions for use into different lines
- Drawings would help or symbols (or chart of meds & time to take)
- Dark background with light/flourescent print (or glow-in-the-dark)
- Print on label with ink that does not fade or disappear
- Yellow or white warning labels are easier to read than red
- Directions could be printed in all CAPS or bold
- Information on label should NOT be written by hand
- Lower and higher case letters are easier to read than ALL CAPS
- Beige background is easier for seniors to read than white
- List emergency phone number on label
- Standard placement of drug expiration date
- Print in braille for visually-imparied patients

QUESTION #5: Other suggestions?

606 surveys returned (132 responses to Question #5) as of January 13, 2009



- Easy-open lids/packages should be used; no child-proof caps for seniors
- Include purpose of drug - state what condition medication is intended to treat
- Bigger or darker font (i.e., drug expiration date, directions for use, warnings)
- Use different color for printing some info (i.e., directions for use, pharmacy phone #)
- Make directions simple/clear/understandable; print in patient's primary language
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Put picture of pill on label or photo of pill or description of pill
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- Different colored bottles or caps would help identify medications
- Standardize location of info so all prescriptions show information in same order
- Make label easy to remove (to recycle bottle or for privacy/security when discarding)
- Note on label when the manufacturer of the medicine changes
- Show where to return outdated meds or option to dispose via phamacy
- Don't cover prescription number with warning labels; use symbols as warnings
- Bottles should be in travel/airplane size; large bottles are clumsy and take up space
- Use top of lid for info; containers opening at bottom leave room for larger label
- Note change in size, color, shape of pills, so won't be perceived as medication error
- State what to do if you miss a dose
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- Labels should be waterproof
- Don't allow label to completely cover bottle; leave space to see medication remains
- Include a plan w/multiple meds (i.e., interactions, don't take with Calcium, etc.)

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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
FORUM ON DESIGNING PATIENT-CENTERED PRESCRIPTION LABELS
MINUTES

DATE: November 20, 2008

LOCATION: Westin Los Angeles Airport Hotel
5400 West Century Boulevard
Lindberg A and B Meeting Rooms
Los Angeles, CA 90045

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, President
D. Tim Dazé Esq., Vice President, Public Member
Shirley Wheat, Public Member
Stanley Weisser, RPh, Treasurer
James Burgard, Public Member
Robert Swart, PharmD

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Kristy Schieldge, Senior Staff Counsel
Robert Ratcliff, Lead Supervising Inspector
Karen Abbe, Analyst
Tina Thomas, Analyst

President Schell called the meeting to order at 1:43 p.m.

President Schell explained that today's forum is being hosted by the California State Board of Pharmacy as part of the board's efforts to develop standards for prescription labels by 2011 that will be patient-centered, and to implement the California Medication Safety Act (SB 472, Corbett, Chapter 470, Statutes of 2007). The goal is to foster better patient understanding of the information on a label as a means to reduce medication errors, and improved patient well-being.

1. Welcoming Remarks

President Schell stated that the Board of Pharmacy takes the Medication Safety Act very seriously and considers it a primary focus. He noted the significant degree of literature and study that has been conducted on the topic of patient-centered labeling. He explained that the board has facilitated forums such as today's in order to gain more input from the public which they serve. This input is needed to ensure that medication labels are designed in a way that will facilitate positive patient outcomes. President Schell stated that the board has a subcommittee in place to focus on the topic. The subcommittee has taken action to conduct surveys and attend outreach events as well in order to receive input from a wide variety of resources.

2. Improving Prescription Container Labels – What is the Status of the Research - (Michael S. Wolf, PhD, MPH and Stacey Cooper Bailey, MPH)

President Schell introduced Dr. Wolf and Ms. Bailey.

The board heard a presentation from Dr. Wolf which detailed the results of a research study conducted by Northwestern University, Louisiana State University and Harvard University over the past several years related to problems patients face when trying to read drug labeling. He added that the focus over the past year has shifted to finding ways to improve prescription drug labeling specifically. He stated that they have conducted several studies to identify specific aspects of how drug instructions are written and how drug labels are organized in order to support patient understanding and use.

Dr. Wolf reviewed current intervention targets, with primary targets being drug warnings and precautions, and "sig" instructions. He reviewed the value of patient-centered drug labels - that they are tangible, brief, repeatedly used, and are the only source of information for many. He shared results of studies which provided the percentage of patients reading their drug labels incorrectly. He described the numerous ways a simple sig can be interpreted, as well as significant dispensing variability based on interpretation by a pharmacist.

Dr. Wolf explained new studies currently in place relating to prescription instructions, drug warnings and precautions, standardized prescribing and improved physician counseling. Dr. Wolf stated the objective of an enhanced prescription label design and explained that the method of studies included an actual-use assessment. Dr. Wolf reviewed the specifics of an enhanced label prototype. The prototype involves a change in cylinder dimensions in order to minimize the "wrap around" of text within the label. He explained, however, that there are major obstacles to implementing such a label in regards to pharmacy software. He stated, however, that when the enhanced labels were provided on prescriptions to patients within their study, the comprehension rate increased

significantly. Dr. Wolf discussed drug warnings and suggested simplified information, which improves a patient's likelihood of understanding their label and adhering to it.

Ms. Bailey explained that, although the majority of their studies have been based around the English-speaking community, they have more recently placed focus on communities with limited English proficiency or are non-English speaking. She reviewed study results of the Latino population with language challenges, and identified specific states with the largest of those populations. Ms. Bailey stated that their studies involved research on pharmacies located within some of the larger Latino populated areas in four states, to assess their ability to translate prescription instructions and labels for those who need it. Within those states, 700 pharmacies were included in the study. Results indicated that 56% of those pharmacies had limited or no language translation capability. Additionally, of the 44% with language translation capability, 61% use a computer based translation program. She noted that the issue of translation capability is not limited to rural areas or areas with a small Latino population.

Dr. Wolf added that they are in the beginning process of developing actual-use assessments similar to those conducted on the English-speaking population and having them translated to be able to conduct similar studies in Spanish. He did not state when those results would be available.

Board Comments:

Mr. Weisser commented on a statistic from Ms. Bailey's presentation, with regard to the percentage of pharmacies that could provide translation services for prescription labels by way of a computer program. He asked how the pharmacies that do not have that capability provide the translation service.

Ms. Bailey responded that there were various sources that those pharmacies used to assist them, including bi-lingual pharmacy staff members and website search engines.

Robert Swart asked if their study included what is required in other states with regard to the prescription label.

Dr. Wolf responded that their research involved discussion with numerous state pharmacy boards, which ultimately resulted in discovering 31 different variations of label requirements. He added that, even with the varying requirements that would need to be taken into consideration, it still appears feasible to accommodate those requirements with the enhanced labeling prototype discussed. He did note the issue of smaller bottles, however, and the challenges with space in relation to the potential of larger font size requirements.

Mr. Weisser commented on the issue of verbiage with relation to medication schedules (i.e. mealtimes, specific times, morning, etc.).

Dr. Wolf responded that it is a very large topic of discussion. He noted that many physicians, for example, are against using mealtimes. He added that there is consensus that the higher priority is to clarify whether or not a medication is to be taken with a meal or not.

Discussion continued regarding the issue of which verbiage should be used to indicate when to take medication.

Jim Burgard asked if the study considered the potential of a standardized size bottle.

Dr. Wolf responded that they did not include that consideration, but would find that to be valuable. He added that it would be best to have a minimum size bottle.

Virginia Herold asked if there is anything that Dr. Wolf can state unequivocally as "this is what we know".

Dr. Wolf referred to a paper in the Annals of Pharmacotherapy, published in 2007. He explained that the paper went through a systematic review of the evidence to date to support the content and format of drug labels. He added that they also have a table which lists issues of recommended font size, bold type, etc. which he can forward to the Board. Dr. Wolf stated that what they have repeatedly found to be most useful to patients, and their understanding of the use of their medication, are the items displayed on the left side of the enhanced label prototype reviewed during the discussion. He noted the importance of indication as a key item that should be included, based on their research.

Robert Ratcliff asked if there has been any consideration to converting to a "zip-loc" type bag instead of bottles.

Dr. Wolf responded that the topic of preventing medication overdoses in pediatrics was recently discussed at a meeting with the Institute of Safe Medication Practices. He stated that the potential of plastics bags might be considered, but more likely with relation to over-the-counter drugs. He added that he has heard discussions involving various packaging solutions, but does not know how that will move forward. He noted his support of the medication bottles manufactured specifically for Target pharmacies.

Ms. Herold referred to a discussion at the prior board meeting, and noted the issue raised by manufacturing companies in the need for medication bottles to be round in order for their equipment to accommodate them. She discussed the

potential to turn the label in the other direction on the bottle, for printing purposes.

Dr. Wolf responded that it would allow for more characters per line in that format.

Public Comments

Larry Lovett referred to labels translated into other languages. He asked if there was any review on the accuracy of the translation, and noted the issue of various "dialects" and uses of terminology amongst different countries and regions.

Ms. Bailey responded that they are hoping to conduct studies on the issue in the future, and noted the hesitation of some pharmacies in translating prescriptions as they are unsure if it will be understood correctly by the patient.

Larry Drechsler stated his support of the enhanced label prototype. He referred to the issue of verbiage in specifying when to take their medication, and noted the importance of ensuring patients take all doses as required by centering the times on something they can relate to. He shared concern over the topic of non-identifiable drugs that lack a stamp, etc. He stated that the markings and design are essential in order to avoid confusion and medication errors. Mr. Drechsler touched on prior discussion of limiting the amount of warning labels. He questioned how that would be accomplished with consideration of legal requirements of many specific warning labels on particularly dangerous drugs.

Dr. Wolf responded on the issue of connecting dosages with mealtimes, as well as the issue of ensuring medications are taken with food when identified as such. He stated the importance of including that information as part of the "sig", rather than as a separate warning label. He agreed with Drechsler's comment on drug design and markings, and noted the importance of ensuring consistency in those markings with relation to generic drugs. Dr. Wolf discussed the items included in the third panel of the prototype, which includes the warning labels. He stated that it would be ideal to gain input from pharmacists and utilize their expertise on what is most important in terms of auxiliary warnings. He discussed the option of noting a label on the bottle, directing the patients to review the inserts provided with their medication which will address warnings, etc.

Tina Tarsitano shared concern over the root of administration, as well as whether the pharmacist has the liberty to alter the directions in relation to indicating the time a patient should take their medication.

Dr. Wolf responded, on the question of root of administration, that further testing is needed. He responded to the question of altering directions from the prescriber by explaining that the goal is to standardize those directions so that there is no need to alter them.

Melvin Snidman asked if labels with translated directions are also provided in English.

Ms. Herold stated that, in California, the requirements for prescription labeling do not specify any requirements in terms of which language(s) instructions must be provided in.

Ms. Bailey stated that similar discussions in New York have indicated that such federal regulations are in place. She deferred to legal counsel for accurate information.

Mr. Snidman noted the issue of causing too much alarm to patients if numerous auxiliary warning labels are included.

Dr. Wolf responded that it is a concern by many physicians, but added that it is also a concern of patients if the information is withheld.

3. Patient Health Literacy in the U.S. and its Impact on Health – Michael Villaire (Institute for Healthcare Advancement)

President Schell introduced Mr. Villaire and provided his background.

Mr. Villaire discussed patient health literacy in the United States, including the impact of low health literacy on health care processes and services.

Mr. Villaire provided definitions on literacy and health literacy and explained that it essentially refers to a person's ability to understand standard health information pamphlets, etc. He reviewed two national surveys on adult literacy. Mr. Villaire explained the three types of literacy – prose, document and quantitative literacy, and explained the four literacy levels (below basic, basic, intermediate and proficient) identified by the National Assessment of Adult Literacy (NAAL). He provided the results of findings from the NAAL Health Literacy studies, with statistics relating to the population's literacy levels as explained. The NAAL statistics indicated, for example, that a person at the "below basic" literacy level would only have a 67% probability of being able to read a medical appointment date on a hospital appointment form. Additionally, a person at the "intermediate" literacy level would only have a 67% probability of understanding what time to take their medications from reading a prescription label. Mr. Villaire provided some of the effects of low health literacy on the population, including how it affects the public's ability to understand many aspects of their healthcare. Specifically, people with low health literacy are twice as likely as others to be hospitalized, more likely to have chronic health issues and less likely to seek treatment.

Public Comments:

Tina Tarsitano referred to the NAAL survey, and asked which languages were most commonly identified in relation to health literacy.

Mr. Villaire stated that the NAAL survey was conducted in English only.

4. **Perspective of the Latino Coalition for a Healthy California to Improve Prescription Container Labeling – Vanessa Cajina (Latino Coalition for a Healthy California)**

Mr. Dazé introduced Ms. Cajina and provided her background.

Ms. Cajina explained that the Latino Coalition for a Healthy California was one of three organizations that initiated the standardization of prescription drug labeling in California.

Ms. Cajina provided the definition of health literacy by the Institute of Medicine. She noted that prescription drugs are regularly used to measure health literacy. She discussed "To Err is Truly Human" – a large-scale research study that tested patient health literacy with relation to prescription instructions. The study also clarified that simplification and explicit dosing instructions are in great need in order to reduce medication errors and increase patient safety. She noted that the study was only conducted in English.

Ms. Cajina provided statistics on languages spoken within California and other states. She discussed measures other states have taken to provide language services in medical settings, and indicated that there are four models in place nationally. Those models include:

- Telephonic interpreting
- Direct interpreter reimbursements
- Direct reimbursement to providers
- Language service agencies and brokers

Ms. Cajina noted that, outside of the medical setting, there have been very few efforts to provide language services. Ms. Cajina also provided statistics on the total Latino population within California.

Ms. Cajina provided history on prescription labeling legislation. She reviewed California's push for medication safety, which included the SCR 49 initiative. She explained that SB 472 was a result of the SCR 49 findings and provided the background on both.

Ms. Cajina reviewed efforts that some pharmacies have done to improve language services, including "talking pill bottles", translated labels provided by Walgreen's and Rite Aid, and printing labels and audio information in other languages. She also acknowledged the efforts being made by the Board of Pharmacy in order to obtain input from the public to improve prescription labeling and, ultimately, patient safety.

5. **Perspective of California's Seniors to Improve Prescription Container Labeling – Ramon Castellblanch (California Alliance for Retired Americans)**

Mr. Dazé introduced Dr. Castellblanch and provided his background.

Dr. Castellblanch explained that the California Alliance for Retired Americans (CARA) has been working on SB 472 for some time, and look forward to continuing to work with the board in the future. He stated that California is being watched by the rest of the country to see what action will be taken on this topic of prescription label standardization. In other countries, it is also matter of "trial and error" He explained that countries in Europe have standardized labels, but continue to revise the standards as they attempt to make improvements and find a solution that will work for everyone.

Dr. Castellblanch indicated that CARA had a convention in October 2008, where two sessions were held to gain input from the senior community on what is most important to them relating to their prescription labels. He noted that there were 30-40 senior citizens in each session. Dr. Castellblanch provided a summary of the feedback given in the sessions, which included visual-friendly formatting (white space, headers, etc.), font size, highlighting, a minimum size bottle and language accessibility. He stated that concern was shared during the sessions over the description of the pill as well as changes in the color and size of pills when changing dosage. He added that there was positive feedback relating to the medication schedule (i.e. breakfast, bedtime). He also noted that additional questions were raised on various topics by the group, such as

- Temperature storage information
- What to do if a patient misses a dose of medicine
- What to do if having dental work completed
- When to get a refill (before they run out)
- Expiration dates

Dr. Castellblanch stated that they hope to have subsequent meetings as were conducted in October. He explained that CARA meets monthly, with a substantial size group in attendance. He added that CARA and their members would be interested in joining with the Board of Pharmacy to conduct future forums and looked forward to continuing to work with them on SB 472.

6. **Summary of Patient Surveys Collected During 2008 by the California State Board of Pharmacy**

Ms. Herold acknowledged Karen Abbe, Public and Licensee Education Analyst, for her efforts in formatting, distributing and compiling the survey results for prescription labeling.

Ms. Herold pointed out the fact that California now has only two years to have standards established and the pharmaceutical industry prepared. She noted that California is the first to establish these standards, and other states will be watching and looking to the California boards for leadership.

Ms. Herold reviewed the factors to be considered in standardizing prescription labels, as mandated by SB 472. Those factors included:

- Medical literacy research
- Improved directions for use
- Improved font types and sizes
- Placement of information that is patient-centered
- Needs of patients with limited English proficiency
- Needs of seniors
- Technology requirements for implementation

Ms. Herold reviewed the SB 472 date requirements, including a report due to the legislature of the board's progress in 2011. Additionally, the board must report the status of implementation to legislature in 2013. She noted the value of this report, as it may be necessary to complete the progress in stages. She explained that the "road map" to the improvement of patient labels is not clearly laid out, and more collaborative work may be necessary. Ms. Herold explained that the regulations will go into effect on January 1, 2011. The goal of the Board of Pharmacy, however, is to have regulations in place in 2009, allowing the software vendors a full year to tailor their software technology to the requirements. She explained that the requirement applies to all California patients acquiring prescription medications, and thus the requirement will apply to pharmacies as well.

Ms. Herold provided the specific requirements according to Business & Professions Code 4076 as it pertains to the prescription label. She explained the subcommittee's responsibilities in terms of the information to be gathered for prescription label standardization. She stated that surveys have been brought to the forum and welcomed assistance from the industry in distribution. Ms. Herold did note, however, that the most successful surveys have been those that are distributed to the public on an individual "one-on-one" basis.

Ms. Herold stated that the first public forum was held in April, 2008 and was held within the author's district. She noted, however, that the turnout to the forum was significantly low. Thus, survey forms were created and distributed through other various venues. Ms. Herold reviewed the survey results to date and noted those items within the label which were listed as the highest importance to the public. Those items included 1) directions for use 2) dosage prescribed and 3) name of the drug as well as others. Additional survey data was reviewed and can be viewed on the board's website. Ms. Herold noted that there were a significant number of surveys completed in other languages as well. She encouraged use of the translated surveys by those who have Spanish speaking constituents.

Public Comments:

Melvin Snidman referred to the requirements from legislature. He suggested an additional requirement that the prescriber's professional degree title and telephone number should be indicated.

Response was provided that the telephone number is a requirement.

Larry Lovett stated that the federal caution requirement was excluded.

Dr. Ratcliff responded that it is only required for controlled substances

Dr. Wolf stated that he hopes the board does not get "bogged down" with details. He reiterated the fact that the rest of the country is watching California and looking to our state for direction. He pointed out that decisions will need to be made that best represent the majority of the public, and that it is not feasible to accommodate all requests given. He noted that too much detail can also create distraction, which causes more harm than good.

Doreena Wong (National Health Law Program) asked if outreach has been done by way of translated surveys and attending events focused on languages besides Spanish.

Ms. Herold listed some of the other events that were focused on specific cultures as well as seniors. She noted that the questionnaire has only been translated into Spanish.

Ms. Wong asked what the deadline is for completion of surveys. She added that she believes there are additional community-based organizations that may be able to assist in collection of input.

Ms. Herold responded that if Ms. Wong would like to assist, please do so as quickly as possible. She added that the data is needed sooner rather than later

and would appreciate being provided with contacts that can assist with distributing surveys to additional constituents.

7. Public Comments for Items Not on the Agenda

Dawn Bronsema (CARA) stated that she attended the CARA convention. She said that she was inspired by the discussion and assisted in collecting surveys. She shared general results of the survey, which included 1) larger font 2) medication schedule 3) purpose of the drug 4) generic name, and 5) description of the pill. She stated that CARA has meetings all over the state several times a year, and have access to a substantial representation of the senior community. She concluded by stating that they are available to help where needed on this important project.

Bryan Hui (Tongon Community Service Center) provided background on the Tongon community, specifically the elder portion of that community which have health issues and are non-English speaking. He shared the experience of an individual from the Tongon community who passed away, as she did not understand and, thus did not follow-through, on her treatment and drug prescription as provided.

Anita Le (PALS For Health) explained that their organization is a language service provider and that they train individuals on language proficiency for the purpose of becoming interpreters. She stated that she was speaking on behalf of PALS for Health, as well as a consumer. She gave examples of her experiences in relation to misunderstandings of medication and how it relates to health literacy. Ms. Le stated that PALS for Health would like to assist the Board of Pharmacy in reaching out to the Asian-American community.

Doreena Wong (National Health Law Program) provided background on their organization. She explained that they have been working with the limited-English and immigrant population for many years, and agreed with the importance of assisting those populations in understanding their medicine. She stated that a webinar was conducted to discuss the efforts being made in addressing the issue of health literacy with relation to language barriers. She noted Title 6 of the 1964 Civil Rights Act. They hope to have the results of a research study available soon, which will indicate the prescription label requirements within each state. She reiterated the connection between decreased health literacy and health outcomes, and that it is exacerbated when language barriers exist. Ms. Wong provided examples of patient illness as a result of poor health literacy and language barriers to the treatment or prescription information provided. She noted that on November 13, 2008 the Attorney General settled with the CVS and Rite Aid to provide translated labels as well as counseling in six different languages. She explained that this decision will result in 2000 CVS and Rite Aid pharmacies providing those services across the country in the near future.

8. Next Steps

The committee will continue with the prescription label surveys and provide a report of the results to the board at the January Board Meeting.

9. Public Comments for Items Not on the Agenda

No public comments were provided.

The board acknowledged Melvin Snidman who has been a pharmacist for 50 years. Dr. Swart provided Mr. Snidman with a Board of Pharmacy 50-year pin.

Mr. Snidman stated that the board is doing a good job. In regards to labeling, there is no simple solution to resolving the issue. He provided an example of child who was not recovering from illness due to a misunderstanding by the parent of how to provide the medicine.

The meeting was adjourned at 4:26 p.m.

Agenda Item 3

Consumer Survey with the Pharmacy Foundation of California

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: January 18, 2009

To: SB 472 Subcommittee

Subject: Review of Survey Results from a Joint Survey Developed by the Pharmacy Foundation of California and the Board of Pharmacy

Recently the board was able to work with the Pharmacy Foundation of California to develop a multiple choice survey of four questions that were available via a radio-sponsored survey. The results of this survey will be shared once the results are available, we hope at this meeting.

Agenda Item 4

California's Requirements for Prescription Container Labels

California State Board of Pharmacy
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www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **January 18, 2009**

To: **SB 472 Subcommittee**

Subject: **California's Requirements for Prescription Container Labels**

As the board develops the regulations to specify the elements of patient-centered prescription labels, it must review and incorporate the requirements for these labels that are specified in Business and Professions Code section 4076.

During this meeting, the subcommittee will review each of these elements and its role in a patient-centered label.

California Business and Professions Code -- Requirements for Prescription Container Labels

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety **Code,** it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety **Code,** it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

4077. (a) Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

(b) Physicians, dentists, podiatrists, and veterinarians may personally furnish any dangerous drug prescribed by them to the patient for whom prescribed, provided that the drug is properly labeled to show all information required in Section 4076 except the prescription number.

(c) Devices that bear the legend "Caution: federal law restricts this device to sale by or on the order of a _____," or words of similar meaning, are exempt from the requirements of Section 4076, and Section 111480 of the Health and Safety Code, when provided to patients in skilled nursing facilities or intermediate care facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(d) The following notification shall be affixed to all quantities of dimethyl sulfoxide (DMSO) prescribed by a physician, or dispensed by a pharmacy pursuant to the order of a physician in California: "Warning: DMSO may be hazardous to your health. Follow the directions of the physician who prescribed the DMSO for you."

(e) The label of any retail package of DMSO shall include appropriate precautionary measures for proper handling and first aid treatment and a warning statement to keep the product out of reach of children.

Agenda Item 5

Timeline for Project Deliverables

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
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www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **January 18, 2009**

To: **SB 472 Subcommittee**

Subject: **Timelines for Project Deliverables**

When SB 472 was enacted, the board had the following general timeline:

2008: conduct public hearings statewide – six meetings were envisioned
2009: develop regulations and adopt the requirements by the end of the year
2010: pharmacies implement requirements to be ready for 1/1/11 implementation
2011: requirements become effective and labels on prescription medicine are compliant

We are on-schedule with respect to this timeline, but there is much work to accomplish in the first half of 2009 to ensure the regulations are fully ready by the end of the year. The sooner the board finalizes the requirements, the more time that will be available to pharmacies to comply with the requirement by January 1, 1011.

Ideally, the rulemaking will be completed before the end of this year. To meet this ambitious deadline:

- by the April Board Meeting, the general requirements for the labels should be in draft form.
- A regulation should be ready by July for board action; if not, a special board meeting may need to be convened in advance of the October Board Meeting.
- Board action to adopt the regulation should occur no later than the October Board Meeting

The board's executive officer and this SB 472 Subcommittee will continue to work with the experts in the field of health literacy and patient-centered label design to develop the regulation's requirements for labels.

Much research material on designing patient-centered labels was already shared with the board in advance of the November 20 Board Meeting Forum on SB 472.

Agenda Item 7

Future Meetings

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **January 18, 2009**

To: **SB 472 Subcommittee**

Subject: Future Meetings of the Subcommittee

The subcommittee will need to move quickly during the first half of 2009 so that the regulations can be promulgated before the end of 2009.

At this time, the next subcommittee meeting has been set for March 12, 2009, at 6 p.m. in Sacramento.

One item that will be discussed during this meeting will be the development of additional meetings needed to complete this process.